DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Maca Plastics, Inc.
Mr. Jesse F. Grooms
Assistant Quality Manager
3455 Cross Road
Winchester, Ohio 45697

Re: K140488
Trade/Device Name: Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: July 23, 2014
Received: August 1, 2014

Dear Mr. Grooms:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140488

Device Name
Contact Lens Case

Indications for Use *(Describe)*
For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfections. Use for storage during chemical disinfections only. Do not use heat disinfection.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K140488 SUMMARY

SPONSOR

Company Name: MACA Plastics Inc

Company Address: 3455 Cross Road
West Union, Ohio 45693

Telephone: (937) 544-8618

Contact Person: Jesse Grooms

Contact Email: jgrooms@macaplastics.com

Summary Preparation Date: 04/10/2014

DEVICE NAME **807.92**

Trade Name: Contact Lens Case

Common/Usual Name: Contact Lens Case

Classification Name: Soft (hydrophilic) contact lens care products

Regulation Number: 886.5928

Product Code: LRX

PREDICATE DEVICE

Legally Marked Equivalent Device

Company	***Device Name***	***K Number***
Arlington Contact Lens Service, Inc.	Contact Lens Case	K120969

DEVICE DESCRIPTION **807.92(a) (4)**

Our contact lens case will consist of a lens base with dual adjoining wells for the containment of fluid. The case covers are two screw top caps. The contact lens case has a capacity of over 3.0 ml, therefore, any contact lens can be submerged into the chambers.

K140488 SUMMARY

DEVICE INTENDED USE

The applicant contact lens case is intended for use by contact wearers or practitioners for storing soft, rigid gas permeable or hard contact lenses. This particular contact lens case is not designed for heat disinfection. It is only designed for chemical disinfection.

COMPARISON OF TECHINICAL CHARACTER

Comparison Elements	**MACA Contact Lens**	**Predicate Device**
Device Name	Multiple Brand Names	Multiple Brand Names
Classification Name	Contact Lens Case	Contact Lens Case
Product Code	LRX	LRX
Comparison Statement	**The applicant device has same classification information as predicate device.**	
Intended Use	The applicant contact lens case is intended for use by contact wearers or practitioners for storing soft, rigid gas permeable or hard contact lenses. This particular contact lens case is not designed for heat disinfection. It is only designed for chemical disinfection.	The predicate contact lens case is to be used by the contact wearer or practitioner for storing soft, rigid gas permeable or hard contact lenses. This particular contact lens case is not designed for heat disinfection. It is only designed for chemical disinfection.
Indications	Storage and disinfection of soft, rigid gas permeable or hard contact lenses.	Storage and disinfection of soft, rigid gas permeable or hard contact lenses.
Disinfection Type	Chemical disinfection, not heat disinfection.	Chemical disinfection, not heat disinfection.
Design	Two adjoining chambers with screw top into which contact lenses are immersed.	Two adjoining chambers with screw top into which contact lenses are immersed.
Main Material	Polypropylene (PP) and Acrylonitrile-Butadiene-Styrene copolymer (ABS)	Polypropylene (PP) and Acrylonitrile-Butadiene-Styrene copolymer (ABS)
Comparison Statement	**The applicant device has a similar design and uses the same materials as the predicate.**	
Screw On Caps	Yes	Yes
R/L indications on chamber bottoms and/or top	Yes	Yes
Non-vented caps	Yes	Yes

CONCLUSION **807.92(b) (3)**

The applicant contact lens case is similar to the predicate device in

- Intended use
- Materials
- Design

The applicant contact lens case introduces no new questions concerning safety and efficacy.